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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,016	05/15/2001	Jane C. Hirsh	21720	4877

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER

1616

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/858,016	HIRSH ET AL
	Examiner Sharmila S. Gollamudi	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 October 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-19,22-29 and 32 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3,5-19,22-29 and 32 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Status of Application***

Power of Attorney received on September 23, 2002, Amendment B received on October 18, 2002, and Supplementary IDS received on November 20, 2002, are acknowledged.

Claims 1-3, 5-19, 22-29, and 32 are included in the prosecution of this application.

Claims 30-31 are cancelled. Note the restriction requirement set forth in office action dated June 11, 2002 in which claims 4 and 20-21 are drawn to non-elected species (capsule). These claims remain non-elected and were erroneously included in the rejection summary.

### ***Claim Rejections - 35 USC § 102***

#### **Rejection of claims 1, 2, 3, 5, 7, 10, 14, 16-18, 27 under 35**

**U.S.C. 102(b) as being anticipated by Chen et al (5558879) is maintained.**

Chen et al discloses a controlled release device that has a compressed core containing a medicament, a membrane coating for sustained delivery, a second coating for sustained release of a medicament, and an outer coating for immediate release (Note abstract and examples). Chen et al teach antihistamine (pseudoephedrine), instant polymers, glidants, and excipients are taught in the formulation (examples).

### ***Response to Arguments***

Applicant argues that Chen describes an osmotic device in which the tablet is coated with a water insoluble polymeric membrane. In contrast, the amended claims recite an outer layer that disintegrates in the patient's mouth.

Applicant's arguments have been fully considered but they are not persuasive.

The examiner points out that the instant claims that are rejected are composition claims and that intended use, i.e. "which dissolves or disintegrates intraorally" and "sublingual or buccal absorption", do not hold patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, the examiner points to the abstract in which Chen teaches a core containing a drug, a first inner layer coating containing a drug and water-insoluble polymer, and a second outer coating layer for immediate release containing a drug and *water-soluble* polymer. Chen's structure is capable of dissolving in the mouth since the polymer taught is water-soluble, contrary to applicant's assertion. Additionally, Chen teaches the same polymers in the outer coating as the recited in instant dependent claims. Lastly, the examiner points out that the instant claim language does not exclude additional layers or components in the device. Therefore, the rejection is maintained.

**Rejection of claims 1-3, 6, 8-11, and 25-29 under 35 U.S.C. 102(b) as being anticipated by Barclay et al (5,053,032) is maintained.**

Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for buccal administration of a drug and a

second region for delivering a drug to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). The reference discloses several drugs (analgesics) that are suitable for the delivery device on column 10, line 50 to column 11, lines 35). Barclay discloses the process of making the device and compression of the layers (example 1). Sodium carbonate is taught in the osmotic device in example 3.

### ***Response to Arguments***

Applicant argues that Barclay describes an osmotic device and such a delivery device uses osmotic effect to force out the active agent. It is argued that Barclay does not teach an outer layer which dissolves or disperses in the mouth.

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, intended use of a device does not hold patentable weight, therefore amendments do not overcome the rejection. Secondly, the examiner points to example 3 in which the overcoat contains a medicament which is completely removed within 15-30 minutes of the being in the oral cavity. Lastly, the examiner points out that instant claim language does not exclude other components such as osmotic agents, in the device.

### ***Claim Rejections - 35 USC § 103***

**Rejection of claims 5, 7, 12-19, 22-24, and 32 under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in combination with Jordan et al (4814181), is maintained.**

***Response to Arguments***

Applicant argues that Jordan describes an osmotic dosage form for fast delivery of a first agent and a slow delivery of a second agent. It is argued that Jordan teaches gastrointestinal delivery and not intraoral delivery.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that Jordan et al is relied upon for its specific teaching of manipulating fast and sustained release layers as indicated in the office action dated July 16, 2002 and does not have to teach all elements of the instant claims, which would render it as anticipatory art. One of ordinary skill in the art would look to Jordan's teachings to teach manipulation of excipients to make a fast or slow layer. One would expect similar results since both Barclay and Jordan teach similar devices. As discussed above, the intended use of the device, i.e. buccal versus gastrointestinal delivery, does not hold patentable weight. Lastly, the examiner points out that instant claim language does not exclude the use of other components in the device.

**Rejection of claims 5, 7, 12-19, 22-24, and 32 under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in combination with Faour et al (6004582), is maintained.**

***Response to Arguments***

Applicant argues that Faour et al describes an osmotic device in which the first agent is surrounded by a semi-permeable membrane. It is argued that the device contains a passageway which is mechanically perforated. Lastly, it is argued that Faour does not teach an outer layer that dissolves in the mouth.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that Jordan et al is relied upon for its specific teaching of manipulating fast and sustained release layers as indicated in the office action dated July 16, 2002. As discussed above, intended use of the device does not hold patentable weight. One would be motivated to expect similar results since both Barclay and Faour teach multi-layer devices.

#### New rejections based on Supplementary IDS

##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1-3, 5, 7, 10, 12, and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 1112737.**

EP discloses a pharmaceutical preparation containing an active core, an intermediate layer containing a flavor signaling system, and an active coat (Note abstract). The active coat layer contains HPMC (Note examples).

***Supplementary IDS***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. GB 800,973 and US patent 5,702,723 are considered to anticipate instant invention.

***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 20, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG  
*mh*  
January 2, 2003

*michael g. hartley*  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER